DATA EVALUATION RECORD

STUDY 10

CHEM 112600 Prohexadione calcium
CAS No. 127277-53-6
FORMULATION-00-ACTIVE INGREDIENT

STUDY MRID 44725214
Perez, R. and J. Patel. September, 1998. Storage stability study of Despropionyl-Prohexadione (KI-5376) in soil in support of field soil dissipation studies. Performed by ADPEN Laboratories, Inc., Jacksonville, FL. Submitted by BASF Corporation. RTP, NC. BASF Reg. No. 97/5310 and Report No. 96140. 55 pp.

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GENERAL:
Freezer storage stability studies are needed to support Subdivision N guideline studies.

CONCLUSIONS:
Ancillary Study - Freezer Storage Stability

1. EFED concludes that this supplemental study (Subdivision N, 164-1) is acceptable.

2. Despropionyl-Prohexadione (KI-5376) is not stable in soil when stored frozen at -23 to 0 °C. The total average corrected recoveries of KI-5376 in soil were 81.2%, 53.3%, 20.8%,

and 0.7% at 1 day, 7 , 21 days, and 12 months, respectively.

3. No additional information on the freezer storage stability of KI-5376 in soil is required at this time.

METHODOLOGY:

California (a San Joaqin soil from Tulare County several miles south from Porterville; RCN 96044, MRID 44725213) control soil core samples from field trials were used in this study. Control soil samples were divided into ninety 20 g samples, fortified with 1.00 ppm KI-5376, and stored frozen at -23 to 0 °C along with unfortified control samples. The storage temperature on two occasions was higher than 0 °C (0 to 8 °C and 0 to 1 °C for 2 hours on 12/12/97 and 1 hour on 1/5/98, respectively, due to a freezer repair. Stored samples were analyzed for KI-5376 at 0 and 6 hours, 1, 2, 7, 15, 21 days, 4, 8, 16, and 21 weeks, and at 12 months. BASF's analytical method D9607 was used for the analysis.

Thawed samples were extracted twice with 50 ml of 0.1 N ammonium bicarbonate, centrifuged, and decanted supernatants were combined. Acidified supernatants to pH 2 were fractionated using a SAX SPE column that was conditioned with methanol and water at pH 2. Samples were eluted with pH 2 water. The eluates were divided into two aliquots from which one was refrigerated and second was fractionated on a conditioned (methanol, DI water, and pH 7-8 analog mixture) ENV-SPE column. Samples were eluted using DI water. The eluate pH was adjusted to pH 2 and again fractionated using ENV-SPE column which this time was conditioned using ethyl acetate, methanol, DI water, and a pH 2 analog mixture. Samples were loaded on the column, first eluates and pH 2 water eluates were discarded, then third eluates, ethyl acetate, were collected. Obtained eluates were extracted twice with 0.5 NaOH. The aqueous extracts were combined, evaporated to dryness, and dissolved in 5 or 10 ml DI water. Before final analysis samples were acidified to pH 2. All samples were analyzed for KI-5376 via HPLC with column switching (100 mm Hypersil ODS C18 column as a precolumn, 250 mm Kromasil C18 column as an analytical column) and UV detection on HP 1050 and 1100 series liquid chromatographs. For integration and calibration of peaks an HP Multi Instrument ChemStation Data System was used.

Procedural recoveries for this analytical method averaged 79.2 ± 8.3% (n=26) of KI-5376. The limits of quantitation were 0.01 ppm of KI-5376.

DATA SUMMARY:

The average corrected recoveries (average corrected recovery = (average stored recovery/average procedural recovery) x 100) of KI-5171 in soil were as follows: time 0: 99.3%, 6 hours: 95.3%, 1 day: 81.2%, 2 days: 72.7%, 7 days: 53.3%, 15 days: 28.3%, 21 days: 20.8%, 1 month: 14.2%, 2 months: 10.9%, 16 weeks: 7.6%, 21 weeks: 7.0%, 9 months: 4.5%, and 12 months: 0.7% (see attached Table 1). Procedural recoveries were corrected for the control sample residues.

REVIEWER'S COMMENTS:

1. Despropionyl-Prohexadione (KI-5376) is not stable in soil when stored frozen at -23 to 0 °C. The total average corrected recoveries of KI-5376 in soil were 81.2%, 53.3%, 20.8%, and 0.7% at 1 day, 7 days, 21 days, and 12 months, respectively.

2. No additional information on the freezer storage stability of KI-5376 in soil is required at this time, however, if the metabolite appears to be of toxicological concern a freezer storage stability study at temperatures below -5 °C, or even lower, may be required.

PROHEXADIONE CALCIUM

DER MRID 44725214

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